

What am I Missing Here?

Thought-Provoking Questions for the Clinical Research Industry

By Norman M. Goldfarb

71. You Can Look It Up

Informed consent forms provide study subjects with clinical trial information. As a practical matter, many study subjects conduct additional research on the Internet. Rather than let them wander off onto all sorts of questionable websites, why not suggest – with suitable disclaimers – that they start with a website, such as healthline.com, that provides legitimate information and identifies other trustworthy websites. Empowered subjects are happy subjects. What am I missing here?

72. Trust Me, I Know of What I Speak

The clinical research industry has largely accepted public registries to provide visibility on both successful and unsuccessful trials. Can the same be said for investigator's brochures? Can we rely on sponsors to disclose negative and ambiguous results of previous studies, especially if previous studies are numerous? FDA regulations [21 CFR 312.23 (5)] require investigator's brochures to include, among other things: (a) a summary of information relating to safety and effectiveness in humans obtained from prior clinical studies, and (b) a description of possible risks and side effects to be anticipated on the basis of prior experience with the drug under investigation or with related drugs. It would be interesting to look at some old investigator's brochures to see how forthcoming they were about unfavorable results that subsequently surfaced in litigation. Do they include a statement to the effect that there are no such unfavorable results to report? If we can't trust the investigator's brochures, how can study subjects trust us? What am I missing here?

73. Tomorrow Is Another Day...Just Like Today

One might think that an industry managing ten-year clinical development programs would think long-term. Today's reality, however, is that the focus is on today; sponsors give little attention to building long-term relationships with investigators, and sites give little attention to building long-term relationships with study subjects. Sponsors should make it the top priority when working with a new site to evaluate and, if appropriate, cultivate that site for future studies. Research sites should think about the value of a study subject for future studies and for introductions to other potential subjects. Not only the long-term but also the short-term relationships will benefit. With a bit of long-term perspective, we can get off the treadmill of short-term emergencies. What am I missing here?

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